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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,894	10/31/2003	Liang C. Dong	ALZ5009USANP	2950

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DEWIPAT INCORPORATED
P.O. BOX 1017
CYPRESS, TX 77410-1017

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,894	DONG ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/07 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4-7, 9-14, 18, 22, 23, 25-28, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Aviv et al (USPN 5,496,811 hereafter '811). The claims are drawn to a drug formulation comprising a hydrophobic drug, an oil phase comprising a saturated fatty acid and a surfactant. The formulation has an average particle size below 1 micron.

4. The '811 patent teaches a drug formulation comprising an oil-in-water submicron emulsion comprising a hydrophobic drug, an oily phase and a surfactant/emulsifier, where the average particle size is from 0.1-0.3 microns (abstract; col. 4, lin. 45-53). The drugs are hydrophobic and include indomethacin, betaxolol or adaprolol (claims 17). The oily phase comprises saturated fatty acids such as vegetable oil and other medium chain triglycerides

having carbohydrate chains of 8-12 carbons (col. 5, lin. 21-30). The surfactant is selected from various common compounds such as polysorbates and Pluronic F68 (col. 5, lin. 65-col. 6, lin. 13). The surfactant is present in a concentration from 0.1-5% by weight of the formulation (claims). The drug is present in a concentration up to 5% by weight of the formulation (claim 18). Regarding the formation of an self-emulsifying emulsion, it is the position of the Examiner that since the same components are applied, in the same way in the same concentrations, the formulation of the '811 patent must also form self-emulsifying emulsions. Self-emulsifying compositions are defined by their stability and particle size. The emulsion of the '811 patent meet both of these parameters as well as the compositional limitations. Regarding the formation of a stable emulsion in an aqueous environment, it is the position of the Examiner that thought the reference is silent to this specific property, the drug formulation of the '811 comprises the same components, in the same concentrations producing an emulsion. Since compositions comprising the same components must perform the same way, it is the position of the Examiner that the drug formulation of the '811 patent anticipates the claims.

5. Claims 1, 2, 4-14, 18, 22, 23, 25-28, 38 and 39 rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al (USPN 6,113,921 hereafter '921). The claims are drawn to a drug formulation comprising a hydrophobic drug, an oil phase comprising a saturated fatty acid and a surfactant. The formulation has an average particle size below 1 micron.

6. The '921 patent teaches a drug formulation comprising an oil-in-water submicron emulsion comprising a hydrophobic drug, an oily phase and a surfactant/emulsifier, where the average particle size is from 0.1-0.3 microns (col. 4, lin. 45-53). The drugs are hydrophobic and

include indomethacin, betaxolol, adaprolol and hydrophobic peptides (col. 7, lin. 10-21). The oily phase comprises saturated fatty acids such as vegetable oil and other medium chain triglycerides having carbohydrate chains of 8-12 carbons (col. 5, lin. 21-30). The surfactant is selected from various common compounds such as polysorbates and Pluronic F68 (col. 5, lin. 41-col. 6, lin. 13). The surfactant is present in a concentration from 0.1-5% by weight of the formulation (claims). The drug is present in a concentration up to 5% by weight of the formulation (claims). Regarding the formation of an self-emulsifying emulsion, it is the position of the Examiner that since the same components are applied, in the same way in the same concentrations, the formulation of the '921 patent must also form self-emulsifying emulsions. Self-emulsifying compositions are defined by their stability and particle size. The emulsion of the '921 patent meet both of these parameters as well as the compositional limitations. Regarding the formation of a stable emulsion in an aqueous environment, it is the position of the Examiner that thought the reference is silent to this specific property, the drug formulation of the '921 comprises the same components, in the same concentrations producing an emulsion. Since compositions comprising the same components must perform the same way, it is the position of the Examiner that the drug formulation of the '921 patent anticipates the claims.

7. Claims 1-6, 9-31, 34-36 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Yiv et al (USPN 6,245,349 hereafter '349). The claims are drawn to a drug formulation comprising a hydrophobic drug, an oil phase comprising a saturated fatty acid and a surfactant. The formulation has an average particle size below 1 micron.

8. The '349 patent discloses a drug formulation comprising an oil component, a surfactant and a drug component (abstract). The formulation can be transformed into an oil-in water emulsion for easier transportation (col. 3, lin. 18-28). The formulation comprises a saturated fatty acid such as Captex in a concentration of 42.55% and a non-ionic surfactant in a concentration of 42.35% (table 7.1). Surfactants include Pluronic poloxamers (col. 6, lin. 6-37). The drugs include amphotericin B, which has a solubility of 750 mL (col. 4, lin. 5-14). The drug formulation has an average particle size from 50-65 nm (col. 5, lin. 1-8). Regarding the improved solubility of the drug in oil rather than water, it is the position of the Examiner that such a limitation would be an inherent feature of any formulation given the same oil and surfactant components. Since the drug formulation of the '349 comprises identical non-ionic surfactants in identical ranges, along with identical saturated fatty acids in identical ranges to the instant claims, it is the position of the Examiner that the formulation of the '349 would inherently increase the solubility of any drug over that of water. Regarding the formation of an self-emulsifying emulsion, it is the position of the Examiner that since the same components are applied, in the same way in the same concentrations, the formulation of the '349 patent must also form self-emulsifying emulsions. Self-emulsifying compositions are defined by their stability and particle size. The emulsion of the '349 patent meet both of these parameters as well as the compositional limitations. For these reasons the disclosures render the claims anticipated.

Response to Arguments

9. Applicant's arguments filed 11/26/07 have been fully considered but they are not persuasive. Applicant argues that:

a. The '811 patent does not anticipate because it does not disclose a self-emulsifying drug formulation and said drug is not in nanoparticulate form.

b. The '921 patent does not anticipate because it does not disclose a self-emulsifying drug formulation and said drug is not in nanoparticulate form.

c. The '349 patent does not anticipated because it does not disclose a self-emulsifying drug formulation and said drug is not in nanoparticulate form.

10. Regarding argument a.–c., it remains the position of the Examiner that the '811,'921 and '349 patents teaches a formulation that meets the limitations of the claims. Applicant argues that the formulation has not been introduced to an aqueous medium, however this is not a feature of the instant claims. The claims are written in open language and can include an aqueous medium. Also the claims are not drawn to a self-emulsifying formulation, but rather a formulation that turns into an emulsion because of the precise concentrations of the fatty acid and surfactant phases. These fatty acid and surfactant concentrations are met by the '811 patent, meaning that the formulation must also meet all of the inherent functional limitations. Likewise the '921 and '349 patents each teach formulations comprising oil and surfactant phases within the concentrations of the instant claims. Regarding the particle size of the formulation, it is the position of the Examiner that even though the patents are silent to the drug compound size before the processing of the respective formulation, the resulting formulations of the prior art all meet the particle size limitations of the instant claims. It is the position of the Examiner that the particle size of the total formulation can be taken as the particle size of the drug compounds as well. The '811 and '921 patents teach formulations with particles having an average size from 0.1-0.3 microns. The '943 patent teaches particles size from 50-65 nm. All of these particles

sizes are an average of all components of the formulation, meaning the oil; fatty acid particles and drug particles al have this particle size. Regarding the formation of a self-emulsifying emulsion, it is the position of the Examiner that since the same components are applied, in the same way in the same concentrations, the formulations of the prior art patents must also form self-emulsifying emulsions. Self-emulsifying compositions are defined by their stability and particle size. The emulsions of the prior art patents meet both of these parameters as well as the compositional limitations. For these reasons the claims remain anticipated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

/Micah-Paul Young/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618